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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/809,497 | 03/26/2004 | Takashi Yamamoto | 011350-334 | 7869 |

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BUCHANAN INGERSOLL PC
(INCLUDING BURNS, DOANE, SWECKER & MATHIS)
POST OFFICE BOX 1404
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EXAMINER

BOUCHELLE, LAURA A

| | |
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| ART UNIT | PAPER NUMBER |
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3763

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/809,497

Applicant(s)

YAMAMOTO ET AL.

Examiner

Laura A. Bouchelle

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/26/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/26/04, 8/17/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 12, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee et al (US 2002/0183738). Chee discloses a catheter for percutaneous insertion comprising a sheath 130 with a lumen 132 extending therein, an injection needle 134 with a beveled edge located at the distal end of an insertion member disposed slidably in the lumen of the sheath with a distal portion capable of protruding from the distal end portion of the sheath, three sets of paired electrodes 136, 138, 140 disposed in the distal portion of the catheter for measuring impedance (Page 8, paragraph 118). See Figs. 12A and 12B. The target tissue of the invention disclosed by Chee is the heart (see abstract).

3. Regarding claim 15, Chee discloses a method for treating the heart including inserting the catheter into the living body and advancing it to the neighborhood of the target tissue (Page 21, Claim 33). Chee further discloses the step of puncturing the target tissue based on measurements from the electrodes (Page 22, Claims 50 and 52). Chee further discloses the step of injecting therapeutic composition into the target tissue (Page 22, Claim 39).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 4, 6, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chee in view of Iancea et al (US 6190360). Claim 2 differs from Chee in calling for the electrodes to be disposed on the distal end of the insertion member. Claim 4, depending from claim 2, also calls for the electrodes to be located on the insertion member. Claim 6 differs in calling for electrodes to be located on both the insertion member and the sheath. Claim 8, depending from claim 6, calls for the pairs of electrodes to be individually parted longitudinally as is depicted by Chee. Iancea discloses a percutaneous insertion catheter comprising a sheath 192 and an inner member 194, wherein electrodes 196 are disposed on the distal end of the insertion member (Col. 8, lines 32-35). Iancea further discloses that this configuration allows the electrodes to be positioned in the treatment location (Col. 8, lines 50-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to place the electrodes of Chee on the insertion member as taught by Iancea so that the electrodes can be positioned at the treatment location.

6. Claims 3, 5, 7, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chee in view of Iancea as applied to claims 2, 4, 6, 8 above, and further in view of Tollner et al (US

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2001/0031942). Claim 3 differs from the teaching of Chee in view of Iancea in calling for the electrodes to be located not less than 1 mm from the leading edge of the insertion needle. Tollner discloses a percutaneous insertion catheter comprising sensing electrodes 6 located approximately 3 mm from the tip 4 of the catheter (Page 2, paragraph 30). This configuration eliminates the disadvantage of electrode configurations that are hard to position by offering increased perceptivity lengthwise (Page 1, paragraph 14). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to place the electrodes of Chee in view of Iancea more than 1mm from the leading edge of the insertion member as taught by Tollner to increase perceptivity lengthwise.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee in view of Lederman (US 2003/0032936). Claim 10 differs from Chee in calling for the distal end portion of the sheath to have a through hole communicating with the lumen. Lederman discloses a catheter 10 with a side through hole 16 in fluid communication with the lumen through which therapeutic or diagnostic agents may be delivered (Page 1, paragraph 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the sheath disclosed by Chee to include a side port as taught by Lederman to deliver therapeutic or diagnostic agents.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee in view of Lederman as applied to claim 10 above. Claim 11 differs from the teachings of Chee in view of Lederman in calling for the through hole to be separated by not less than 1 mm from the end face

of the distal end portion. At the time the invention was made, it would have been an obvious matter of design choice to place the through hole not less than 1 mm from the end face. Applicant has not disclosed that this distance serves any advantage or particular purpose of solves a stated problem. Furthermore, one of ordinary skill would expect the device of Chee in view of Lederman to perform equally well with the through hole placed in any location. Therefore, it would have been prima facie obvious to modify the device of Chee in view of Lederman as specified in claim 11 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Chee in view of Lederman.

9. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chee in view of Hill et al (US 6165164). Claim 13 differs from Chee in calling for the catheter to comprise a puncture-sensing device. Claim 14, depending from claim 13 calls for one of the pair of electrodes to be positioned more proximal than the others. This feature is disclosed by Chee. See Fig. 12A. Hill discloses a catheter for injecting therapeutic or diagnostic agents into the heart comprising a tip electrodes mounted at the distal end that are connected to conductors used for measuring electric potentials within the heart for cardiac mapping capable of sensing puncture (Col. 2, lines 56-64). Hill further discloses that this device allows for precise positioning within the heart (Col. 1, lines 6-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the catheter disclosed by Chee to have a puncture sensing device as taught by Hill so that the therapeutic or diagnostic agent can be placed at a precise location within the heart.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura A Bouchelle
Examiner
Art Unit 3763


NICHOLAS D. LUCCHESI
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